

REMARKS

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-21 are still pending in this application. No new matter has been added by this amendment.

The applicants acknowledge and appreciate the indication of allowable subject matter for claims 2, 4 and 6-12.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE 35 U.S.C. 112, 2nd PARAGRAPH REJECTION HAS BEEN OVERCOME

Claims 5, 15, 17, 18 and 20 were rejected as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. To the extent these rejections were understood, the applicants have amended the claims without changing the scope of the claim in order to advance prosecution of the application.¹

III. THE 35 U.S.C. 112, 1st PARAGRAPH REJECTION HAS BEEN OVERCOME

Claims 13-21 were rejected as allegedly indefinite for being enabling for inhibition of a TNF- α receptor, but does not reasonably provide enablement for treating or preventing all diseases mediated by this receptor. The applicants request reconsideration of this rejection for

¹ MPEP 2173.02 states in part "...[t]he examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph is whether the claim meets the threshold requirements of clarity and precision, *not whether more suitable language or modes of expression are available*. When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. *Examiners are encouraged to suggest claim language to applicants to improve clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement.*" (emphasis added)

these claims as these claims are directed to composition claims *not method of use claims* (claims 13-21 have been amended to more clearly define that these are composition claims).

The statement of intended use in the claim is merely a preamble which does not serve to function as a structural limitation of the composition. It is well known that “[w]here a patentee uses the claim preamble to recite structural limitations of his claimed invention, the PTO and courts give effect to that usage. *See id.*; *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed.Cir.1989). **Conversely**, where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, **the preamble is not a claim limitation**. *See Bell Communications*, 55 F.3d at 620; *Kropa v. Robie*, 38 C.C.P.A. 858, 187 F.2d 150, 152, 88 USPQ 478, 481 (1951).” *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1554 (Fed. Cir. 1997)(emphasis added).

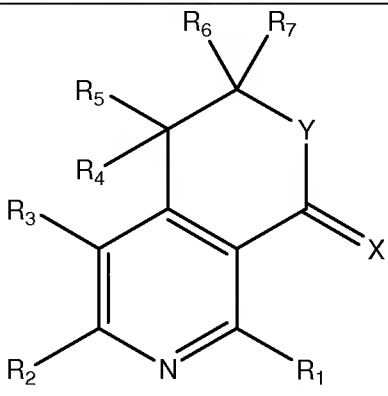
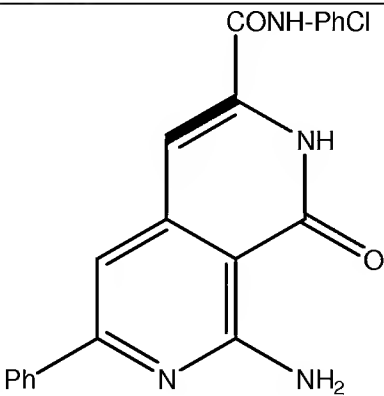
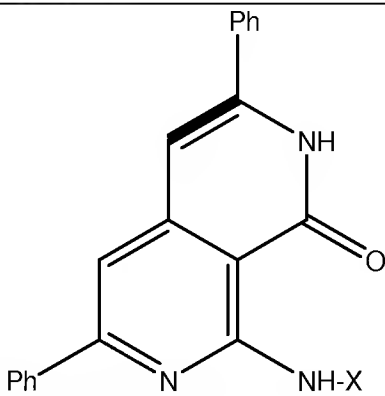
Here, the applicants have defined elements for their composition (e.g. in claim 13, a compound of formula 1 or its pharmaceutically acceptable salt and a pharmaceutically acceptable carrier). One of ordinary skill in the art would be able to make the compositions of the invention without undue experimentation as the compounds of formula 1 have been adequately described in the specification and pharmaceutical carriers are well known to those of skill in the art.

IV. THE 35 U.S.C. 102(b) REJECTION HAS BEEN OVERCOME

Claims 1 and 3 were rejected as allegedly being anticipated by Elmaati et al. (Journal of Chinese Chemical Society (Taipei, Tawian), (2002), 49(6), 1045-1050 - “Elmaati”). The applicants request reconsideration of this rejection for the following reasons.

Claims 1 and 3 were rejected as allegedly being anticipated by Van Allan et al. (Journal of Heterocyclic Chemistry (1970), 7(3), 495-507 - “Van Allan”). The applicants request reconsideration of this rejection for the following reasons.

Neither Elmaati nor Van Allan teach all of the elements of the applicants’ claimed compounds (see comparative chart on next page):

Formula 1 of claim 1	Elmaati	Van Allan
		
		X = -Bu-n or -CH ₂ Ph

As can be seen from the comparative chart, both Elmaati and Van Allan differ at least by having an extra degree of unsaturation in the compounds and therefore do not anticipate claims 1 or 3.

V. THE 35 U.S.C. 103(a) REJECTION HAS BEEN OVERCOME

General note: Several of the rejections relied upon a holding of homology. However, the assertion of homology was in error, i.e. homology does not include a comparison of the presence or absence of a -CH₃ moiety, but represents a series of organic compounds in which each successive member has one more CH₂ group in its molecule than the preceding member (see *Hawley's Condensed Chemical Dictionary*, page 656, (2007)), e.g. -CH₂CH₃ (ethyl) vs. -CH₂CH₂CH₃ (propyl)

A. Claim 1 was rejected as allegedly being obvious by Trommer et al. (Tetrahedron Letters (1973), (17), 1447-8 -"Trommer"). The applicants request reconsideration of this rejection for the following reasons.

Trommer differs from the claims as amended in that the nitrogen of the pyridine ring is methylated in Trommer, but is a free amine in the applicants' claims. As noted above, this relationship is not one of homology.

Trommer also differs from the applicants' invention in that the amide (-C(=O)-NH-) ring has an extra degree of unsaturation which is not present in the applicants' claimed invention (similar to the difference exhibited by Elmaati and Van Allan – see figures above in section IV).

Trommer also differs in that the corresponding position for the variable R₆ or R₇ of the applicants' claimed compound in Trommer is a -CO₂⁻ moiety which is not encompassed by the applicants' scope of R₆ or R₇.

As such, Trommer does not teach or suggest all of the elements of the applicants' claimed compounds. Therefore, the applicants' claimed invention is not rendered obvious by Trommer.

B. Claim 1 was rejected as allegedly being obvious by Birkofer et al. (Chemische Berichte (1957), 90, 2933-40 -"Birokfer"). The applicants request reconsideration of this rejection for the following reasons.

Birkhofer differs from the claims as amended in that the nitrogen of the pyridine ring is methylated in Birkhofer, but is a free amine in the applicants' claims. As noted above, this relationship is not one of homology.

Birkhofer also differs from the applicants invention in that the amide (-C(=O)-NH-) ring has an extra degree of unsaturation which is not present in the applicants' claimed invention (similar to the difference exhibited by Elmaati and Van Allan – see figures above in section IV).

As such, Birkhofer does not teach or suggest all of the elements of the applicants' claimed compounds. Therefore, the applicants' claimed invention is not rendered obvious by Birkhofer.

C. Claims 1 and 3 were rejected as allegedly being obvious by Govindachari et al. (Journal of the Chemical Society (1957) 551-6 -"Govindachari") or Eugster et al. (Helvetica Chimica Acta (1957), 40, 69-79 -"Eugster"). The applicants request reconsideration of this rejection for the following reasons. As Govindachari and Eugster refer to the same compound, these rejections are addressed together.²

Both Govindachari and Eugster both differ from the claims as amended in that the nitrogen of the pyridine ring is methylated in Govindachari and Eugster, but is a free amine in the applicants' claims. As noted above, this relationship is not one of homology.

² MPEP 904.03 states in part "[i]n selecting the references to be cited, the examiner should carefully compare the references with one another and with the applicant's *disclosure* to avoid the citation of an unnecessary number. The examiner is not called upon to cite *all* references that may be available, but only the "best." (37 CFR 1.104(c).) Multiplying references, any one of which is as good as, but no better than, the others, adds to the burden and cost of prosecution and should therefore be avoided." (emphasis added)

An additional difference is that the corresponding position for the applicants' variable R_3 in the compound of Govindachari and Eugster is an alkene ($-\text{CH}=\text{CH}_2$) which is excluded from the scope of the claims as amended.

As such, neither Govindachari or Eugster teach or suggest all of the elements of the applicants' claimed compounds. Therefore, the applicants' claimed invention is not rendered obvious by either Govindachari and Eugster.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution. The Commission is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,
FROMMER LAWRENCE & HAUG LLP

By: /Howard C. Lee/
Ronald R. Santucci Howard C. Lee
Reg. No. 28,988 Reg. No. 48,104
Telephone: (212) 588-0800
Facsimile: (212) 588-0500